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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,042	07/25/2003	Michael Marquant	RDID 0208 I US	4047
Brent A. Harris Roche Diagnostics Corporation Bldg. D 9115 Hague Road Indianapolis, IN 46250-0457				
EXAMINER HYUN, PAUL SANG HWA				
ART UNIT 1797				
PAPER NUMBER				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/628,042

Applicant(s)

MARQUANT ET AL.

Examiner

PAUL S. HYUN

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-8, 11-22 and 24-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8, 11-22 and 24-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 20, 2008 has been entered.

Claims 1-4, 6-8, 11-22 and 24-28 are currently pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims **1-4, 6-8 and 11-22** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites that the claimed device comprises at least one channel. However, the structural relationship between the claimed channel and the claimed transport and support layers is unclear.

It is suggested that claim 1 include the following claim limitation to clarify the structural relationship between the channel and the transport and support layers: "...each transport layer comprises a channel wherein the channel is defined by a space between two sections of a transport layer".

Claim 3 recites that each channel is defined by a space between two sections of a transport layer. According to claim 3, there is a 1 to 1

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correspondence between the number of transport layers and the number of channels. Yet, claim 1 recites that the claimed device comprises one or more layers and a plurality of transport layers. In summary, the limitations recited in claim 3 contradict the limitations recited in claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **24** is rejected under 35 U.S.C. 103(a) as being unpatentable over Chow (US 6,167,910) in view of Arnold et al. (US 6,210,986 B1).

Chow discloses a microfluidic device for conducting fluid analysis. The device comprises a plurality of layers (e.g. five layers, see Abstract), wherein the layers are staggered in a step-like manner (see Fig. 2) and each layer comprises a microfluidic channel formed therein (see Fig. 4). Each channel can comprise a layer of insulating material (see line 36, col. 4) or electrodes (see lines 24-26, col. 3). The device disclosed by Chow differs from the claimed invention in that the sidewalls of the channels are not defined by a gap between two pieces of material. Rather, the channels disclosed by Chow are formed by etching grooves into individual substrates.

Arnold et al. disclose a microfluidic device comprising multi-layered channels (see Fig. 6C). The sidewalls of the channels are defined by a gap between two pieces of spacers 230. Arnold et al. disclose that etching produces channels that are wider at the top than at the bottom whereas channels formed by spacers exhibit a more uniform width (see lines 1-10, col. 2). In light of the disclosure of Arnold et al., it would have been obvious to one of ordinary skill in the art to form the channels disclosed by Chow using spacers rather than etching.

Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Arnold et al. as applied to claim 24, and further in view of Ekström et al. (US 5,376,252).

Neither Chow nor Arnold et al. disclose an insulating layer that is in the form of a foil material.

Ekström et al. disclose a microfluidic device comprising an insulating layer 2 made from electrically insulating foil (see lines 60-65, col. 3). In light of the disclosure of Ekström et al., it would have been obvious to one of ordinary skill in the art to use a foil material as the insulating layer in the modified Chow device to minimize the thickness of the device.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Arnold et al. as applied to claim 24, and further in view of Yager et al. (US 6,482,306 B1).

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Neither Chow nor Arnold et al. disclose an electrode in the form of a coating.

Yager et al. disclose a microfluidic channel comprising electrodes wherein the electrodes are coated to the channel surface (see claim 11). In light of the disclosure of Yager et al., it would have been obvious to one of ordinary skill in the art to incorporate the electrodes disclosed by Chow as a coating to minimize the thickness of the microfluidic device.

Claims **27 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Chow in view of Arnold et al. and Yager et al. as applied to claim 26, and further in view of Oloman et al. (US 4,118,305).

None of Chow, Arnold et al. and Yager et al. disclose a hydrophilic insulating material comprising perforations.

Oloman et al. disclose an electrochemical device for conducting reactions wherein the device comprises an electrode, a counter electrode and a porous, hydrophilic insulating material separating the two electrodes (see claim 1). The porous insulating material permits free flow of liquid between the electrodes while providing electrical insulation between the electrodes. In light of the disclosure of Oloman et al., it would have been obvious to one of ordinary skill in the art to provide a hydrophilic, porous insulating layer around the electrodes of the modified Chow device so that flow of liquid to the electrodes is permitted while providing electrical insulation.

Allowable Subject Matter

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Claims **1-4, 6-8 and 11-22** would be allowable if rewritten or amended to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter:

Chow discloses a microfluidic device for conducting fluid analysis. The device comprises a plurality of layers wherein the layers are staggered in a step-like manner and each layer comprises a microfluidic channel formed therein. However, Chow does not disclose layers of electrodes arranged in a step-like manner. The staggered arrangement disclosed by Chow provides an unobstructed window to the optical detection area of each channel (see lines 5-8, col. 13). Based on the disclosure, there is no motivation or suggestion to stagger the layers such that the electrodes are exposed despite the fact that the channels disclosed by Chow comprise electrodes.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

/Paul S Hyun/
Examiner, Art Unit 1797